

REMARKS

Applicants note that all amendments, cancellations, and additions of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),¹ and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

In the office action dated 7/2/04, the Examiner made a number of rejections. The rejections are listed below in the order in which they are herein addressed.

(1) Claims 1, 3-13, and 37 are rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement;

(2) Claims 1, 3-4, 9-11, 25, 27-28 and 37 are rejected under U.S.C. 102 (e) as allegedly being anticipated by Sabatini (U.S. Patent 6,544,790, hereinafter Sabatini);

(3) Claims 1, 3, 5-6, 8, 12, 25, 27, 29, 31-32, 38-40 and 42 are rejected under U.S.C. 103 (a) as allegedly being obvious in light of Sabatini in view of Hawley-Nelson et al. (U.S. Patent 5,736,392; hereinafter Hawley-Nelson);

(4) Claims 6, 13, 30 and 41 are rejected under U.S.C. 103 (a) as allegedly being obvious in light of Sabatini in view of Hawley-Nelson and further in view of Wagner et al. (Proc. Natl. Acad Sci USA 89:7934 (1992); hereinafter Wagner); and

(5) Claims 1, 3-4, 8-12, 25, 27-28 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over Claims 8-15 of copending Application No. 10/123,435.

¹ 65 Fed. Reg. 54603 (Sept., 8, 2000).

I. The Claims are Enabled

The Examiner has rejected Claims 1, 3-13, and 37 under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement (Office Action, pg. 2). In particular, the Examiner states "because the specification, while being enabling for a method of transfecting a eukaryotic cell, said method comprising the method steps recited in claims 1, 12, 13, or 37, does not reasonably provide enablement for a method of transfecting any cell...." Office Action, pg. 2. The Applicant respectfully disagrees and submits that the claims are enabled as currently written. However, in order to further the business interests of the Applicant and while reserving the right to prosecute the original (or similar) claims in the future, the Applicant has amended independent Claims 1, 12, 13 and 37 to include the element of the cell to be transfected being a eukaryotic cell. As the Examiner has admitted that such claims are enabled, the Applicant respectfully requests that the rejection be withdrawn.

II. The Claims are Not Anticipated

The Examiner has rejected Claims 1, 3-4, 9-11, 25, 27-28 and 37 under U.S.C. 102 (e) as allegedly being anticipated by Sabatini (Office Action, pg. 5). The Applicant respectfully disagrees and submits that the claims are not anticipated by Sabatini. However, in order to further the business interests of the Applicant and while reserving the right to prosecute the original (or similar) claims in the future, the Applicant has amended independent Claims 1, 11, 25 and 37 to include the element of "wherein said DNA binding molecule is covalently linked to said ligand for a receptor." Sabatini does not teach or suggest the claim element of a ligand for a receptor covalently bound to a DNA binding molecule. As such, the Applicant respectfully requests that the rejection be withdrawn.

III. The Claims are Not Obvious

The Examiner has issued several rejections under U.S.C. 103 (a). The Applicant submits that the Examiner has failed to provide a *prima facie* case of obviousness. The combination of references referred to by the Examiner fails to provide a *prima facie* showing of obviousness as required by § 2143 of the Manual of Patent Examining Procedure (MPEP). There are three criteria that must be met to provide *prima facie* obviousness. The first of these criteria is a

suggestion or motivation in the references or the knowledge generally available to combine the reference teachings. The second criteria is that the prior art must teach or suggest all the claim limitations. The third criteria is a reasonable expectation of success should the combination be carried out. Applicants submit that the Examiner has failed to set forth a *prima facie* case of obviousness because these criteria have not been met.

Each of the Examiner's obviousness rejections is addressed separately below.

A. Claims 1, 3, 5-6, 8, 12, 25, 27, 29, 31-32, 38-40 and 42 are not Obvious

The Examiner has rejected Claims 1, 3, 5-6, 8, 12, 25, 27, 29, 31-32, and 38-40 as allegedly being anticipated by Sabatini in light of Hawley-Nelson. The Applicant respectfully disagrees and submits that the Examiner has failed to demonstrate a *prima facie* case of obviousness. However, in order to further the business interests of the Applicant and while reserving the right to prosecute the original (or similar) claims in the future, the Applicant has amended independent Claim 12 to include the element of "wherein said DNA binding molecule is covalently linked to said ligand for a receptor." As described above, Claims 1, 11, 25 and 37 have also been amended to include this element.

In particular, the Applicant submits that the Examiner has failed to provide a motivation to combine the teachings of Sabatini and Hawley-Nelson to arrive at the presently claimed invention. For example, the Examiner has admitted that "Sabatini et al. do not specifically teach that the transfection complex comprising [sic] penton protein as a ligand for a receptor (the elected species) or the ligand is covalently linked to a cationic protein or that the transfection complex further comprising [sic] targeting molecules or one or more cationic lipids as additional complexing agents." (Office Action, pg. 9).

Indeed, Sabatini teaches away from the claim element of ligand for a receptor that is covalently linked to a DNA binding protein by teaching complexes that comprise gelatin and nucleic acids in the absence of DNA binding agents. Sabatini does not teach or suggest the covalent attachment of any components of a transfection reaction. At best, Sabatini teaches the use of gelatin as a carrier protein (See e.g., Column 9, lines 19-20 of Sabatini²). If the gelatin as used in Sabatini was covalently attached to any other component of the reaction, it would fail to

² "The carrier for use in the methods of the present invention can be, for example, gelatin or an equivalent thereof."

serve as a carrier. This is in direct contrast to the methods of the present invention which employ a ligand for a protein covalently attached to DNA binding molecule, which serves to target the DNA to the cell. Hawley-Nelson further teaches away from the presently claimed invention by teaching only reactions performed in solution, rather than on a surface, as the presently claimed invention describes. Furthermore, the Examiner has pointed to no specific teaching in either Sabatini or Hawley-Nelson to combine the teachings. To sustain a rejection the Patent Office has the obligation to specifically point out such teaching.

The Applicant respectfully submits that by making these conclusory statements, the Examiner has not provided any evidence as to why a skilled artisan would make the combination. The Examiner has only stated what he believes each reference teaches in isolation from the other references and then stated that it would be obvious to combine the elements. In order to support the combination, the Examiner has merely relied on the level of skill in the art. This is not permissible. Such unsupported statements are exactly what the Federal Circuit in *In re Rouffet*, 149 F.3d 1350 (Fed.Cir. 1998) sought to prevent. The Federal Circuit stated:

The Board did not...explain what specific understanding or technological principal within the knowledge of one of ordinary skill in the art would have suggested the combination. Instead, the Board merely invoked the high level of skill in the art. If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technological advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness."

To properly support the rejection, the Examiner must provide concrete evidence (*e.g.*, statements from the prior art, other references, a declaration attesting to the Examiner's personal knowledge, etc.) of a motivation to combine. Without such evidence, the rejection must be withdrawn. Considering that Hawley-Nelson does not teach surface reactions and Sabatini does not teach a ligand for a receptor covalently bound to a DNA molecule, such a showing cannot be made.

Furthermore, the Applicant submits that, even if Sabatini and Hawley-Nelson are improperly combined, the references do not provide a reasonable expectation of success. In particular, the Applicant submits that Hawley-Nelson does not provide a reasonable expectation

of success if the transfection methods described are combined with the surface methods of Sabatini. Unlike the present invention, Hawley-Nelson teaches only reactions in solution. There is no expectation or teaching in Hawley-Nelson that would lead one skilled in the art to believe that the solution-based methods of Hawley-Nelson would work on a surface. The Federal Circuit has stated in numerous decisions that the standard for obviousness is not "obvious to try," for example:

"of course an 'obvious' to try' standard is not a legitimate test of patentability....The statutory standard of § 103 is whether the invention, considered as a whole, would have been obvious to one skilled in the art, not whether it would have been obvious to one skilled in the art to try various combinations."³

The court further stated:

"An 'obvious to try' situation exists when a general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued."⁴

In conclusion, the Applicant submits that the Examiner has not provided a *prima facie* case of obviousness because the Examiner has not provided a motivation to combine Hawley-Nelson and Sabatini with a reasonable expectation of success. As such, the rejection should be withdrawn.

B. Claims 6, 13, 30, and 41 are not Obvious

The Examiner has rejected Claims 6, 13, 30 and 41 as allegedly being anticipated by Sabatini in light of Hawley-Nelson and further in view of Wagner (Office Action, pg. 11). The Applicant respectfully disagrees and submits that the Examiner has failed to demonstrate a *prima facie* case of obviousness. In particular, the Applicant submits that the Examiner has failed to provide a motivation to combine the teachings of Wagner with the teachings of Sabatini and Hawley-Nelson. As described above, Sabatini does not teach or suggest a ligand for a receptor covalently linked to a DNA binding molecule. Indeed, Sabatini teaches away from the claim element of ligand for a receptor that is covalently linked to a DNA binding protein by teaching complexes that comprise gelatin and nucleic acids in the absence of DNA binding agents.

³ *N.V. Akzo v. E.I. du Pont de Nemours and Co.*, 810 F.2d 1148, 1151, 1 USPQ2d 1704, 1707 (Fed. Cir. 1987)

⁴ *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990)

Sabatini does not teach or suggest the covalent attachment of any components of a transfection reaction. Wagner further teaches away from the presently claimed invention by teaching only reactions performed in solution, rather than on a surface, as the presently claimed invention describes. Furthermore, the Examiner has pointed to no specific teaching in Sabatini, Hawley-Nelson, or Wagner to combine the teachings. As described above, the case law is clear that the Examiner has an obligation to specifically point out such teaching.

Furthermore, even if the references are improperly combined, the Applicant submit that the references do not provide a reasonable expectation of success, should the combination be carried out. In particular, the Applicant submits that Wagner does not provide a reasonable expectation of success if the transfection methods described are combined with the surface methods of Sabatini. Unlike the present invention, Wagner teaches only reactions in solution. There is no expectation or teaching in Wagner that would lead one skilled in the art to believe that the solution-based methods of Wagner would work on a surface. As described above, the Federal Circuit has stated in numerous decisions that the standard for obviousness is not, as the examiner has attempted to apply, a standard of "obvious to try." As such, the Applicant submits that the Examiner has failed to provide a prima facie case of obviousness and respectfully requests that the rejection be withdrawn.


II. The Claims are not Subject to Double Patenting

Claims 1, 3-4, 8-12, 25, 27-28 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 8-15 of copending Application No. 10/123,435. The Applicant respectfully disagrees. However, in order to expedite prosecution while not acquiescing to the Examiner's arguments, the Applicant has filed herewith a terminal disclaimer over Application No. 10/123,435. As such, the rejection is moot.

CONCLUSION

If a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call the undersigned collect at (618) 218-6900.

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